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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>Customer No.:</i>	23643	}	
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<i>Group:</i>	1618	}	
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<i>Confirmation No.:</i>	9879	}	
		}	
<i>Application No.:</i>	10/765,336	}	FILED ELECTRONICALLY:
		}	February 1, 2010
<i>Patent No.:</i>	7,601,332	}	
		}	
<i>Invention:</i>	VITAMIN RECEPTOR BINDING DRUG DELIVERY CONJUGATES	}	
		}	
<i>Inventor:</i>	Iontcho R. Vlahov, et al.	}	
		}	
<i>Filed:</i>	January 27, 2004	}	
		}	
<i>Attorney Docket:</i>	20150-74359	}	
		}	
<i>Examiner:</i>	Dameron Levest Jones	}	

PETITION UNDER 37 C.F.R. § 1.181

Mail Stop Petitions
Director for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This Petition under 37 C.F.R. § 1.181 is being filed to assert the Patentees' claim to additional Patent Term Adjustment (PTA) under 35 U.S.C. 154(b) for the above-identified U.S. Patent Application Serial No. 10/765,336 (now U.S. Patent No. 7,601,332, issued October 13, 2009). On January 7, 2010, the U.S. Court of Appeals for the Federal Circuit issued a decision in *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010). In its decision, the Federal Circuit affirmed the U.S. District Court of the District of Columbia's holding that the U.S. Patent and Trademark Office (USPTO) has misinterpreted 35 U.S.C. 154(b), resulting in an incorrect calculation of PTA for many issued patents. *Id.* at 1.

As set forth below, the PTA for the above-identified patent was incorrectly calculated by the USPTO. Accordingly, this Petition is filed to assert a claim to the additional PTA that was incorrectly omitted by the USPTO upon issuance of the patent. According to the provisions of 37 C.F.R. § 1.181(a)(1), this Petition is taken to the Director from the improper dismissal of the requests for reconsideration of PTA by an examiner in the Office of Patent Legal Administrations, an action that “is not subject to appeal to the Board of Patent Appeals and Interferences or to the court.” Furthermore, according to the provisions of 37 C.F.R. § 1.181(a)(2), this Petition is taken to the Director when a statute (i.e., 35 U.S.C. § 154(b)(3)) specifies that “the matter is to be determined directly by ... the Director.” Moreover, according to the provisions of 37 C.F.R. § 1.181(a)(3), this Petition is filed to “invoke the supervisory authority of the Director” and rectify the USPTO’s incorrect calculation of PTA for the above-identified patent. This Petition is timely filed according to the provisions of 37 C.F.R. § 1.181(f). That is, this petition is filed within two months of the December 17, 2009 decision of the USPTO dismissing Patentees’ request for correction of the USPTO’s determination of the adjusted term accorded this patent.

Statement of Facts

The USPTO issued a Notice of Allowance for the above-referenced application on June 23, 2009. The Notice of Allowance indicated that the PTA was 478 days. On June 26, 2009, Patentees filed an initial Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d), asserting that the application was entitled to 1,055 days of PTA instead of 478 days as incorrectly calculated by the USPTO. On August 24, 2009, the initial Request was dismissed as premature.

On October 13, 2009, the above-identified patent issued from the application. The Issue Notification for the above-identified patent again indicated that the PTA was 478 days. On November 11, 2009, Patentees timely filed a second Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d), asserting that the application was entitled to 1,055 days of PTA instead of 478 days as incorrectly calculated by the USPTO. On December 17, 2009, the second Request was dismissed.

As stated previously, in the two Requests for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d), the above-identified patent is entitled to **1055 days** of

PTA instead of 478 days as incorrectly calculated by the USPTO. The correctly calculated PTA (i.e., 1055 days) was determined according to the grounds for adjustment under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b) and was calculated according to the periods of adjustment under 37 C.F.R. § 1.703(a) and 37 C.F.R. § 1.703(b). Furthermore, the correctly calculated PTA is established according to the recent decision by the U.S. Court of Appeals for the Federal Circuit in *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010). A summary of the correctly calculated PTA is below.

	Relevant Dates	Period of Adjustment
Examination Delay under 37 C.F.R. § 1.702(a)	<p><i>37 C.F.R. § 1.703(a)(1)</i></p> <p>Filing date of patent application: <u>January 27, 2004</u></p> <p>Fourteen months after filing date of patent application: <u>March 27, 2005</u></p> <p>First Action mailed by USPTO: <u>January 17, 2007</u></p>	Difference for which patentee should receive credit: <u>+ 661 days</u> ,
Examination Delay under 37 C.F.R. § 1.702(b)	<p><i>37 C.F.R. § 1.703(b)</i></p> <p>Filing date of patent application: <u>January 27, 2004</u></p> <p>Three years after filing date of patent application: <u>January 27, 2007</u></p> <p>Date of filing an RCE by Applicant: <u>August 26, 2008</u></p>	Difference for which patentee should receive credit: <u>+ 577 days</u> ,
Circumstances under 37 C.F.R. § 1.704(b)	<p><i>37 C.F.R. § 1.704(b)</i></p> <p>Request for a three-month Extension of Time</p> <p>Office Action mailed by USPTO: <u>June 29, 2007</u></p> <p>Three-month due date: <u>September 29, 2007</u></p> <p>Response received by USPTO:</p>	Difference for which §1.702 period of adjustment should be reduced: <u>-75 days</u>

	Relevant Dates	Period of Adjustment
	<u>December 13, 2007</u>	
Circumstances under 37 C.F.R. § 1.704(b)	<p><i>37 C.F.R. § 1.704(b)</i></p> <p>Request for a two-month Extension of Time</p> <p>Office Action mailed by USPTO: <u>March 26, 2008</u></p> <p>Three-month due date: <u>June 26, 2008</u></p> <p>Response received by USPTO: <u>August 26, 2008</u></p>	Difference for which §1.702 period of adjustment should be reduced: <u>-61 days</u>
Circumstances under 37 C.F.R. § 1.704(b)	<p><i>37 C.F.R. § 1.704(b)</i></p> <p>Request for a two-month Extension of Time</p> <p>Office Action mailed by USPTO: <u>October 29, 2008</u></p> <p>Three-month due date: <u>January 29, 2009</u></p> <p>Response received by USPTO: <u>March 17, 2009</u></p>	Difference for which §1.702 period of adjustment should be reduced: <u>-47 days</u>
Total PTA as of Date of Filing an RCE by Applicants		<u>1055 days</u>

Pursuant to the decision rendered in *Wyeth v. Kappos*, a patentee is entitled to PTA credit for examination delay under 37 C.F.R. § 1.702(a) in addition to any examination delay under 37 C.F.R. § 1.702(b), to the extent that the two periods of delay do not occur on the same calendar day or days. A copy of *Wyeth* is attached hereto as “Attachment A” for the Office’s convenience.

Accordingly, the Patentees of the above-identified patent are entitled to a credit for the sum of 661 days under 37 C.F.R. § 1.702(a) and 577 days under 37 C.F.R. § 1.702(b), for a total of 1238 days, subject to a reduction of 183 days under 37 C.F.R. § 1.704. Thus, the Patentees respectfully submit the total PTA is **1055 days** and request that the Director review the

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Petition under 37 C.F.R. § 1.181

erroneous dismissal of the previously submitted Requests for Reconsideration of Patent Term Adjustment. In light of the Federal Circuit's decision in *Wyeth v. Kappos*, the Director is requested to take action and grant the correctly calculated PTA of **1055 days** to the Patentees instead of the incorrectly calculated PTA of 478 days.

The Patentees believe that no fees are required with the filing of this Petition. However, if fees are due, the Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 10-0435, with reference to our Matter No. 20150-74359.

Respectfully submitted,

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